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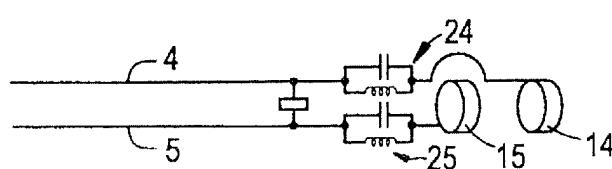
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(54) Title: SYSTEMS AND METHODS FOR MAGNETIC-RESONANCE-GUIDED INTERVENTIONAL PROCEDURES



(57) Abstract: Herein is disclosed a probe, including a first electrode disposed at least partially on the probe surface, a second electrode disposed at least partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a reactive element electrically coupling the first conductor and the second conductor.

***SYSTEMS AND METHODS FOR
MAGNETIC-RESONANCE-GUIDED INTERVENTIONAL PROCEDURES***

CROSS-REFERENCE TO RELATED APPLICATIONS

5 [01] This application is a continuation-in-part of U.S. Patent Application Serial No. 09/428,090, filed November 4, 1999, which claims the benefit of priority to U.S. Provisional Patent Application Serial No. 60/106,965, filed November 4, 1998. This application also claims benefit of priority to U.S. Provisional Patent Application Serial No. 60/283,725, filed April 13, 2001. The aforementioned applications are
10 incorporated herein in their entireties by this reference.

BACKGROUND

[02] The disclosed systems and methods relate in general to ablation and electrophysiologic diagnostic and therapeutic procedures, and in particular to systems and methods for performing, guiding, and providing visualization of such procedures.
15 [03] Atrial fibrillation and ventricular tachyarrhythmias occurring in patients with structurally abnormal hearts are of great concern in contemporary cardiology. They represent the most frequently encountered tachycardias, account for the most morbidity and mortality, and, despite much progress, remain therapeutic challenges.
[04] Atrial fibrillation affects a larger population than ventricular tachyarrhythmias,
20 with a prevalence of approximately 0.5% in patients 50-59 years old, increasing to 8.8% in patients in their 80's. Framingham data indicate that the age-adjusted prevalence has increased substantially over the last 30 years, with over 2 million people in the United States affected. Atrial fibrillation usually accompanies disorders such as coronary heart disease, cardiomyopathies, and the postoperative state, but
25 occurs in the absence of any recognized abnormality in 10% of cases. Although it may not carry the inherent lethality of a ventricular tachyarrhythmia, it does have a mortality twice that of control subjects. Symptoms which occur during atrial fibrillation result from the often rapid irregular heart rate and the loss of atrio-ventricular (A-V) synchrony. These symptoms, side effects of drugs, and most

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importantly, thrombo-embolic complications in the brain (leading to approximately 75,000 strokes per year), make atrial fibrillation a formidable challenge.

[05] Two strategies have been used for medically managing patients with atrial fibrillations. The first involves rate control and anticoagulation, and the second

5 involves attempts to restore and maintain sinus rhythm. The optimal approach is uncertain. In the majority of patients, attempts are made to restore sinus rhythm with electrical or pharmacologic cardioversion. Current data suggest anticoagulation is needed for 3 to 4 weeks prior to and 2 to 4 weeks following cardioversion to prevent embolization associated with the cardioversion. Chronic antiarrhythmic therapy may
10 be indicated once sinus rhythm is restored. Overall, pharmacologic therapy is successful in maintaining sinus rhythm in 30 to 50% of patients over one to two years of follow-up. A major disadvantage of antiarrhythmic therapy is the induction of sustained, and sometimes lethal, arrhythmias (proarrhythmia) in up to 10% of patients.

15 [06] If sinus rhythm cannot be maintained, several approaches are used to control the ventricular response to atrial fibrillation. Pharmacologic agents which slow conduction through the AV node are first tried. When pharmacologic approaches to rate control fail, or result in significant side effects, ablation of the AV node, and placement of a permanent pacemaker may be considered. The substantial incidence of
20 thromboembolic strokes makes chronic anticoagulation important, but bleeding complications are not unusual, and anticoagulation cannot be used in all patients.

[07] In addition to medical management approaches, surgical therapy of atrial fibrillation has also been performed. The surgical-maze procedure, developed by Cox, is an approach for suppressing atrial fibrillation while maintaining atrial functions.

25 This procedure involves creating multiple linear incisions in the left and right atria. These surgical incisions create lines that block conduction and compartmentalize the atrium into distinct segments that remain in communication with the sinus node. By reducing the mass of atrial tissue in each segment, the mass of atrial tissue is insufficient to sustain the multiple reentrant rotors, which are the basis for atrial
30 fibrillation. Surgical approaches to the treatment of atrial fibrillation result in an efficacy of > 95% and a low incidence of complications. However, despite these

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encouraging results, this procedure has not gained widespread acceptance because of the long duration of recovery and risks associated with cardiac surgery.

[08] Invasive studies of the electrical activities of the heart (electrophysiologic

studies) have also been used in the diagnosis and therapy of arrhythmias. Focal atrial

5 tachycardias, AV-nodal reentrant tachycardias, accessory pathways, atrial flutter, and idiopathic ventricular tachycardia can be cured by selective destruction of critical electrical pathways with radiofrequency (RF) catheter ablation. Electrophysiologists have attempted to replicate the maze procedure using RF catheter ablation. The procedure is arduous, requiring general anesthesia and procedure durations often

10 greater than 12 hours, with exposure to ionizing x-ray irradiation for over 2 hours.

Some patients have sustained cerebrovascular accidents. One of the main limitations of the procedure is the difficulty associated with creating and confirming the presence of continuous linear lesions in the atrium. If the linear lesions have gaps, then activation can pass through the gap and complete a reentrant circuit, thereby

15 sustaining atrial fibrillation or flutter. This difficulty contributes significantly to the long procedure durations discussed above.

[09] Creating and confirming continuous linear lesions and morbidity could be facilitated by improved minimally-invasive techniques for imaging lesions created in the atria. Such an imaging technique may allow the procedure to be based purely on

20 anatomic findings.

[10] The major technology for guiding placement of a catheter is x-ray

fluoroscopy. For electrophysiologic studies and ablation, frame rates of 7-15 per second are generally used which allows an operator to see x-ray-derived shadows of the catheters inside the body. Since x-rays traverse the body from one side to the

25 other, all of the structures that are traversed by the x-ray beam contribute to the image. The image, therefore is a superposition of shadows from the entire thickness of the body. Using one projection, therefore, it is only possible to know the position of the catheter perpendicular to the direction of the beam. In order to gain information about the position of the catheter parallel to the beam, it is necessary to use a second

30 beam that is offset at some angle from the original beam, or to move the original beam to another angular position. Since x-ray shadows are the superposition of

contributions from many structures, and since the discrimination of different soft tissues is not great, it is often very difficult to determine exactly where the catheter is within the heart. In addition, the borders of the heart are generally not accurately defined, so it is generally not possible to know if the catheter has penetrated the wall of the heart, and lesions are invisible under x-ray fluoroscopy. Thus, it is very difficult to discern whether tissue has been adequately ablated. The intracardiac electrogram may be used to guide the catheters to the proper cardiac tissue.

5 [11] Intracardiac ultrasound has been used to overcome deficiencies in identifying soft tissue structures. With ultrasound it is possible to determine exactly where the 10 walls of the heart are with respect to a catheter and the ultrasound probe, but the ultrasound probe is mobile, so there can be doubt where the absolute position of the probe is with respect to the heart.

15 [12] Neither x-ray fluoroscopy nor intracardiac ultrasound have the ability to accurately and reproducibly identify areas of the heart that have been ablated.

20 [13] A system known as "non-fluoroscopic electro-anatomic mapping" (U.S. Patent No. 5,391,199 to Ben-Haim), was developed to allow more accurate positioning of catheters within the heart. That system uses weak magnetic fields and a calibrated magnetic field detector to track the location of a catheter in 3-space. The system can mark the position of a catheter, but the system relies on having the heart not moving 25 with respect to a marker on the body. The system does not obviate the need for initial placement using x-ray fluoroscopy, and cannot directly image ablated tissue.

25 [14] Magnetic resonance imaging (MRI) is a known imaging technique which uses high-strength magnetic and electric fields to image the body. A strong static magnetic field orients the magnetic moments of the hydrogen nuclei creating a bulk nuclear magnetization. RF magnetic field pulses with frequency tuned to the resonant or "Larmor" frequency in the presence of the static field, change the spatial orientation 30 of the bulk magnetization of the nuclei, as known to those skilled in the art. In addition, time-varying gradient magnetic fields applied in the three Cartesian directions (X, Y, Z) are used for spatial encoding of the signals from the tissue. The magnitude of a gradient magnetic field is such as to cause the main static magnetic field to vary linearly as a function of the respective spatial coordinate in the magnet.

As a result of the addition of the static and gradient magnetic fields, the local Larmor resonance frequency, is spatially encoded. The information corresponding to the strength of the magnetization at each point in space can then be decoded by means of reconstruction techniques known to those skilled in the art, permitting the imaging of 5 tissues in three-dimensional space.

[15] MRI has been used to guide procedures in which RF energy is applied to non- contractile organs such as the brain, liver and kidneys to ablate tumors. However, these systems are not suitable for use in the heart. U.S. Patent No. 5,323,778 to 10 Kandarpa et al. discloses a method and apparatus for MRI and tissue heating. There is no provision in the disclosed probe for measuring electrical signals, and it is unclear how much resolution is provided by the probe.

SUMMARY

[16] The systems and methods disclosed herein enhance the art by, among other things, facilitating the performance of multiple functions during electrophysiological 15 interventions with MRI. An embodiment provides an instrument that can be easily visualized and/or tracked in an MR or other image. An embodiment provides an instrument that can be easy to maneuver. An embodiment provides an instrument that can facilitate high resolution imaging of a target area. An embodiment provides an instrument that can record an intracardiac electrogram. An embodiment provides an 20 instrument that can deliver RF energy for ablation of the desired tissue near the instrument tip.

[17] An embodiment provides an improved multi-functional systems and methods for guiding and/or providing visualization during electrophysiologic procedures.

[18] In an embodiment, the disclosed systems and methods facilitate guiding or 25 visualizing ablation procedures suitable for use in, e.g., the heart and other structures.

[19] In an embodiment, the disclosed systems and methods include catheters that are easy to maneuver and/or track.

[20] In an embodiment, the disclosed systems and methods facilitate imaging ablation lesions with increased resolution of the target area and reliability.

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[21] In an embodiment, the disclosed systems and methods facilitate delivering RF energy for ablation of tissue, including but not limited to pathologic tissue.

[22] In an embodiment, the disclosed systems and methods facilitate recording and monitoring electrical potentials, including but not limited to physiologic bio-potentials.

[23] In an embodiment, the disclosed systems and methods facilitate determining the position of, e.g., target tissue or an ablation instrument.

[24] In an embodiment, the disclosed systems and methods facilitate guiding the delivery of RF ablation energy.

10 [25] In an embodiment, the disclosed systems and methods facilitate the integration of imaging and ablation in a single instrument.

[26] In an embodiment, the disclosed systems and methods facilitate using magnetic resonance imaging to increase the safety and accuracy of electrophysiologic procedures.

15 [27] In an embodiment, the disclosed systems and methods provide an invasive multi-functional electrophysiology and imaging antenna catheter which includes an RF antenna for receiving magnetic resonance signals, a loop antenna for device tracking, an ablation tip for delivering RF energy for ablation procedures, and diagnostic electrodes for receiving physiological electrical potentials. The combined 20 electrophysiology and imaging antenna catheter can be used in combination with a MRI scanner to, for example, guide, perform, and/or provide visualization during electrophysiologic diagnostic or therapeutic procedures.

25 [28] In an embodiment, the disclosed systems and methods can be particularly applicable to ablation of atrial and ventricular arrhythmias, and in such embodiments may be used as an intracardiac device to both deliver energy to selected areas of tissue and visualize the resulting ablation lesions, thereby greatly simplifying production of continuous linear lesions. Additionally, the disclosed systems and methods can be used as active tracking devices by means of a "loop antenna" that receives MRI signals excited by the scanner. Gradient echoes are then generated along three 30 orthogonal axes to frequency encode the location of the coil and thus provide the three-dimensional (3D) space coordinates of the electrode tip. These numeric

coordinates can then be used to control the imaging plane of the scanner, thereby allowing accurate imaging slices to be prescribed to target anatomy for RF therapy.

Low resolution images can be obtained indicating catheter location relative to the body by combining the MRI signals from the loop with those of the conventional

5 external MRI detector coil. In addition, high resolution images can be obtained using the signals from the loop antenna. In another embodiment, the loop antenna utilized in the combined electrophysiology and imaging catheter for receiving MRI signals is connected to form a "loopless" type antenna. High-resolution images from the antenna may be combined with low-resolution images from surface coils of the MR

10 scanner to produce a composite image. The disclosed systems and methods further include embodiments useful for guiding electrophysiologic diagnostic and therapeutic procedures other than ablation. An RF filtering system is provided for suppressing the MRI signal while not attenuating the RF ablative current. Steering means may be provided for steering the invasive catheter under MR guidance. Steering could be

15 facilitated by providing a probe with a pull wire. In addition, the disclosed systems and methods include acquisition of local physiological bio-potential measurements using a multi-electrode catheter, which permits, via MRI guidance, active tracking of the location of each electrode. A central novel feature of the disclosed systems and methods is that because bio-potentials, RF ablation, and MRI are each performed over

20 different frequency ranges, frequency-dependent circuit elements can be used to change the catheter's electrical structure enabling it to provide multiple electrical structures within a single physical structure.

[29] In an embodiment, a probe or catheter includes a first electrode disposed at least partially on the probe surface, a second electrode disposed at least partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a reactive element electrically coupling the first conductor and the second conductor.

[30] In an embodiment, a magnetic resonance imaging probe includes a coaxial cable having an inner conductor and an outer shield, a first split ring electrode electrically coupled to the inner conductor, and a second split ring electrode electrically coupled to the outer conductor, a first center split ring electrode

electrically coupled to the first split ring electrode and to a first conductor, a second center split ring electrode electrically coupled to the first center split ring electrode and to the second split ring electrode, and also coupled to a second conductor.

[31] In an embodiment, a magnetic resonance imaging probe includes a first 5 electrode disposed on the probe surface, a second electrode disposed on the probe surface, a first conductor electrically coupled to the first electrode through a reactance, a second conductor electrically coupled to the second electrode through a reactance, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted 10 between the first conductor and the second conductor.

[32] In an embodiment, a system for magnetic resonance imaging includes a magnetic resonance imaging probe, having a first electrode disposed on the probe surface, a second electrode disposed on the probe surface, a first conductor 15 electrically coupled to the first electrode through a reactance, a second conductor electrically coupled to the second electrode through a reactance, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor; and an interface electrically coupled to the probe, the interface having a tuning/matching/decoupling circuit and a signal splitting circuit; 20 and an MRI scanner electrically coupled to the interface.

[33] In an embodiment, a magnetic resonance imaging probe includes a coaxial cable having an inner conductor and an outer shield, and a split ring electrode having a first portion and a second portion, the first portion being electrically coupled to the inner conductor, and the second portion being electrically coupled to the outer shield.

[34] In an embodiment, a magnetic resonance imaging probe may include a coaxial cable having an inner conductor and an outer shield, a first split ring electrode 25 electrically coupled to the inner conductor, and a second split ring electrode electrically coupled to the outer conductor, wherein the first split ring and the second split ring are electrically coupled by a first reactive element.

[35] In an embodiment, the reactive element can conduct a high frequency signal 30 between the first conductor and the second conductor. In an embodiment, the high

frequency signal has a frequency higher than about 10 MegaHertz (MHz). In an embodiment, the reactive element can conduct a signal having magnetic resonance imaging frequency energy between the first conductor and the second conductor.

[36] In an embodiment, at least one of the first conductor and the second conductor can conduct a low frequency signal to at least one of the first electrode and the second electrode. In an embodiment, the low frequency signal has a frequency of up to about 500 kiloHertz (kHz). In an embodiment, the low frequency is in the range from about 100 Hertz (Hz) to about 1 kHz. In an embodiment, the frequency is about 100 kHz.

[37] In an embodiment, the reactive element conducts a signal having ablation frequency energy to at least one of the first electrode and the second electrode. In an embodiment, the reactive element conducts a signal having biopotential recording frequency energy to at least one of the first electrode and the second electrode.

[38] In an embodiment, the probe further comprises a lumen.

[39] In an embodiment, the reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor. In an embodiment, the reactance comprises at least one of an inductor and an LC circuit.

[40] In an embodiment, the first conductor couples to the first electrode through a reactance. In an embodiment, at least one of the first conductor, the second conductor, the first electrode, and the second electrode comprises at least one of a magnetic resonance compatible material, a superelastic material, copper, gold, silver, platinum, iridium, MP35N, tantalum, titanium, Nitinol, L605, gold-platinum-iridium, gold-copper-iridium, and gold-platinum.

[41] In an embodiment, the first conductor and the second conductor are electrically coupled to a tuning/matching/decoupling circuit. In an embodiment, the first conductor and the second conductor are electrically coupled to a signal splitting circuit. In an embodiment, the first conductor and the second conductor are electrically coupled by at least one capacitor.

[42] An embodiment may further include a third conductor electrically coupled to a third electrode, and a fourth conductor electrically coupled to a fourth electrode, wherein a first signal having high frequency energy is conducted between the first conductor and the second conductor through the reactive element, and a second signal

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having low frequency energy is conducted to at least one of the third electrode and the fourth electrode.

[43] An embodiment may further include a shaft, the shaft including at least one of Kevlar, nylon, Teflon, polyethylene, polyolefin, PTFE, polyurethane, PEBAK,

5 braided Kevlar, and braided nylon. In an embodiment, the probe surface is covered by a lubricious coating.

[44] In an embodiment, the probe has an outer diameter in the range of about 1 French to about 15 French. In an embodiment, the probe has a length in the range of about 50 cm to about 200 cm. In an embodiment, the probe further comprises a pull 10 wire.

[45] In an embodiment, the first conductor, the reactive element, and the second conductor form a loop antenna. In an embodiment, the first conductor, the reactive element, and the second conductor form a loopless antenna.

[46] In an embodiment, the inner conductor and the outer shield are electrically coupled by a reactive element. In an embodiment, the reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor. In an embodiment, the inner conductor and the outer shield are electrically coupled by a second reactive element. In an embodiment, the second reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor. In 20 an embodiment, the first reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor.

[47] In an embodiment, a method for simultaneously imaging and ablating a tissue can include exposing the tissue to a magnetic field, the field having a static component and a gradient component, placing a probe adjacent to the tissue, the probe including a first electrode disposed at least partially on the probe surface, a second electrode disposed at least partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted 25 between the first conductor and the second conductor, and low frequency energy is conducted to at least one of the first electrode and the second electrode; directing low- 30

frequency energy to the probe, the low frequency energy being conducted to the tissue by at least one of the first electrode and the second electrode; and receiving high-frequency energy from at least one of the first conductor and the second conductor for imaging at least one of the probe and the tissue.

5 [48] In an embodiment, a method for simultaneously imaging a tissue and measuring a bioelectric potential in the tissue may include exposing the tissue to a magnetic field, the field having a static component and a gradient component, placing a probe adjacent to the tissue, the probe including a first electrode disposed at least partially on the probe surface, a second electrode disposed at least partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor, and low frequency energy is conducted to at least one of the first 10 electrode and the second electrode; receiving low-frequency energy from the probe, the low frequency energy being conducted from at least one of the first electrode and the second electrode; and receiving high-frequency energy from at least one of the first conductor and the second conductor for imaging at least one of the probe and the tissue.

15 [49] In an embodiment, a method for simultaneously imaging a tissue, ablating the tissue, and measuring a bioelectric potential in the tissue may include exposing the tissue to a magnetic field, the field having a static component and a gradient component, placing a probe adjacent to the tissue, the probe including a first electrode disposed at least partially on the probe surface, a second electrode disposed at least 20 partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor, and low-frequency and medium-frequency 25 energy is conducted to at least one of the first electrode and the second electrode; receiving low-frequency energy from the probe, the low frequency energy being 30

conducted from at least one of the first electrode and the second electrode, directing medium-frequency energy to the probe, the medium-frequency energy being conducted to the tissue by at least one of the first electrode and the second electrode, and receiving high-frequency energy from the probe, the high-frequency energy having magnetic resonance imaging data.

[50] In an embodiment, a method for simultaneously imaging and treating a tissue may include exposing the tissue to a magnetic field, the field having a static component and a gradient component, placing a probe adjacent to the tissue, the probe including a first electrode disposed at least partially on the probe surface, a second

10 electrode disposed at least partially on the probe surface, a first conductor electrically coupled to the first electrode, a second conductor electrically coupled to the second electrode, and a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor; delivering a therapy to the 15 tissue, and receiving high-frequency energy from the probe, the high-frequency energy having magnetic resonance imaging data.

[51] In an embodiment, the therapy may include at least one of ablation energy, heat, ultrasound energy, a substance discharged through a lumen of the probe, and monitoring the delivering.

20 BRIEF DESCRIPTION OF THE DRAWINGS

[52] Embodiments of the disclosed systems and methods will be apparent from the following more particular description of preferred embodiments as illustrated in the accompanying drawings, in which some reference characters refer to the same parts throughout the various views. The drawings are not necessarily to scale, emphasis 25 instead being placed upon illustrating principles of the disclosed systems and methods.

[53] FIGs. 1A-1G show physical and electrical diagrams of a probe or catheter.

[54] FIGs. 2A-2I show physical and electrical diagrams of a probe or catheter and of an interface.

[55] FIG. 3 shows a block diagram illustrating a system for magnetic resonance imaging.

[56] FIG. 4 shows data comparing the signal-to-noise ratio performance of some exemplary embodiments.

5 [57] FIG. 5 shows imaging and/or tracking data according to an embodiment.

[58] FIG. 6 shows imaging and/tracking data and biopotential data according to an embodiment.

DETAILED DESCRIPTION

10 [59] The disclosed systems and methods in an embodiment use MRI to allow multi-functional catheters to be placed without radiation, and provides very accurate localization of catheter tips in 3D space. With current MRI scanners, resolution is limited by the distance the RF coil is from the volume of tissue being imaged. The signal from any particular imaging volume is picked up by an external detector coil.

15 The gradients select a volume inside the body for imaging, but the coil outside the body picks up the signal from the imaging volume as well as the noise from all of the sample regions that are within its range. The farther the surface coil is from the imaging volume, the more noise can be present.

[60] MRI has been proposed as an alternative imaging modality for guiding and 20 monitoring EP procedures and offers several advantages over other modalities for electrophysiologic intervention. For example, the heart and endocardial landmarks can be visualized throughout the procedure. This anatomical information facilitates the identification of ablation sites for arrhythmias such as atrial flutter and fibrillation. In addition, cardiac motion and flow dynamics can be monitored during the 25 procedure. This enables acute assessment of cardiac function as the intervention is performed. Furthermore, MRI does not employ ionizing radiation, such as x-rays, and is generally considered to be a minimal risk procedure.

[61] MRI can facilitate the visualization of ablated tissue during the procedure. 30 Because lesions are typically invisible under x-ray fluoroscopy, it is currently difficult to discern whether tissue has been completely ablated, is only temporarily stunned

(i.e., has been subjected to reversible thermal injury), or indeed has not been treated at all. By actually visualizing the tissue lesion, MRI enables positive confirmation of tissue treatment. This can be especially important for procedures that benefit from continuous lines of ablation, such as treatment for atrial flutter, atrial fibrillation, and 5 isolation of pathologic tissue in the pulmonary veins. Imaging of ablated tissue may allow what are now long and difficult procedures to be performed on a more routine and efficient basis.

[62] In an embodiment, an internal catheter receiving coil/antenna may be incorporated into an electrophysiologic RF ablation catheter that also includes 10 electrodes for recording bio-potentials. Because the receiving coil/antenna is closer to the imaging volume being targeted for ablation and may have a limited range of detection, the MRI signal is increased and the noise from remote regions reduced, thereby providing an enhanced signal-to-noise ratio (SNR), which enables higher strength MRI gradients to be applied, thereby improving resolution where it is needed 15 most.

[63] In an embodiment, MRI can be used to facilitate catheter ablation of atrial fibrillation by guiding creation of continuous linear ablation lesions, and confirming that a complete linear lesion has been created (line of block) in combination with 20 measurements of bio-potential. The visualization of areas of ablation and measurements of bio-potential may allow a reduction in the number of lesions needed, and may also reduce the number of recurrences, by more accurately ablating the arrhythmias.

[64] A reactive element can include an electrical component such as a capacitor, a 25 resistor, an inductor, a diode, or various combinations of these. A reactive element can be a filter, such as a lowpass filter, a highpass filter, a bandpass filter, or a bandstop filter. A reactance can be a reactive element.

[65] A high frequency signal or high frequency energy can include energy that has 30 a frequency of 10 MegaHertz (MHz) or higher. It can include energy that has a frequency of 60 MHz or higher. It can include energy that has a frequency of about 63.9 MHz.

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[66] A low frequency signal or low frequency energy can include energy that has a frequency of less than 10 MHz. It can include energy that has a frequency of 500 kiloHertz (kHz) or less. It can include energy that has a frequency of 100 kHz or less. It can include energy that has a frequency of 1 kHz or less. It can include energy that

5 has a frequency of 100 Hertz (Hz) or less.

[67] Ablation frequency energy can include energy that has a frequency of less than 10 MHz. It can include energy that has a frequency of 500 kiloHertz (kHz) or less. It can include energy that has a frequency of 100 kHz or less. It can include energy that has a frequency of 1 kHz or less. It can include energy that has a frequency of 100

10 Hertz (Hz) or less.

[68] Biopotential recording frequency energy can include energy that has a frequency of less than 10 MHz. It can include energy that has a frequency of 500 kiloHertz (kHz) or less. It can include energy that has a frequency of 100 kHz or less. It can include energy that has a frequency of 1 kHz or less. It can include energy that

15 has a frequency of 100 Hertz (Hz) or less. It can include energy that has a frequency between about 100 Hz and about 1 kHz.

[69] Medium frequency energy can include energy that has a frequency of less than 10 MHz and greater than 50 kHz. It can include energy that has a frequency between 500 kiloHertz (kHz) and 50 kHz. It can include energy that has a frequency between

20 200 kHz and 50 kHz. It can include energy that has a frequency of 100 kHz.

[70] A catheter can be a probe. A probe can be a catheter.

[71] In an embodiment, a lubricious material can include at least one of polyvinylpyrrolidone, polyacrylic acid, hydrophilic substance, or silicone.

[72] FIG. 1A depicts the physical structure of a probe or catheter according to an

25 embodiment. A probe 10 can be about 10 cm to about 1000 cm long. The probe 10

can be from about 50 cm to about 200 cm long. The probe can be 100 cm long. The probe 10 can be a catheter. The probe 10 may have two surface electrodes 14, 15.

The surface electrodes 14, 15 may be ring electrodes. The , are located at the distal end, 15, and two wire leads, 4 and 5, run the length of the catheter. The electrical

30 structure of a conventional electrophysiology catheter is shown in FIG. 1b. Note that the electrical leads 4 and 5, terminate in respective surface electrodes, 14 and 15.

This arrangement can be less preferred for MRI studies because of (i) potential safety issues arising from heating induced in the wires and electrodes by the MRI excitation field; (ii) application of RF energy for ablation may result in significant degradation and interference during MRI scanning; and (iii) the elements are not tuned to the MRI

5 frequency and generally will not provide improved SNR and MRI resolution performance. Interfering signals and noise not related to MRI detection should be limited, as should be currents induced directly in the conductors by the time-dependent MRI fields. MRI tracking may be facilitated by creating a small, confined region of high SNR.

10 [73] It is known to those skilled in the art that long, flexible loop antennas produce local regions of high signal and are therefore ideal for active catheter tracking (For example, see Atalar E, Bottomley PA, Ocali O, Correia LC, Kelemen MD, Lima JA, Zerhouni EA. High resolution intravascular MRI and MRS by using a catheter receiver coil. *Magn Reson Med.* 1996;36:596-605). For a catheter structure with two
15 electrical leads, a loop antenna configuration can be produced by short-circuiting the distal end of the catheter. While this solution may be theoretically ideal, it is unacceptable for electrophysiology interventions because in order to perform ablation and to record of bio-potentials, multiple, electrically isolated wire leads are preferred.

[74] In an embodiment, a capacitor 20, is placed at the distal end 11, of the catheter

20 (FIG 1c). In another preferred embodiment, in addition to the capacitor 20 at the distal end of the catheter, RF reactances 24 and 25 are applied in series with each of the surface electrodes 14 and 15, in order to improve the safety of the device for MRI applications. The component values of the reactances 24 and 25 are adjusted or tuned such as to produce a high impedance at the MRI frequency, but low impedance at the
25 frequency used for RF ablation and/or measuring bio-potentials. More specifically, in one embodiment, each of the reactances 24 and 25 may include a non-magnetic RF inductor. In another preferred embodiment, each of the reactances 24 and 25 may include an RF inductor-capacitor pair, preferably non-magnetic, connected in parallel to form a parallel resonant LC circuit with resonant tuned to substantially equal to the

30 MRI frequency, for example, 63.9 MHz with a static magnetic field of 1.5 Tesla. By this means each LC pair provides a high impedance at the MRI frequency. The LC

circuit can be formed by winding a wire coil around a ceramic chip capacitor. For maximum effectiveness, the LC circuit should be shielded with conducting foil or the like.

[75] Element 20 can also be a reactive element.

5 [76] To understand the function of the catheter, it is useful to consider the electrical appearance of the device at both low and high frequency ranges. First, at low frequencies, the capacitor has a large impedance and behaves approximately as an open circuit. The RF inductors have low impedance and appear as short circuits. Therefore, the low frequency structure (FIG. 1d) of the catheter behaves the same as

10 the conventional structure (FIG. 1a). The electrodes can thus be used for monitoring bio-potentials, and applying RF ablation at frequencies, for example, that are lower than the MRI frequency (for example, less than about 15 MHz for RF ablation vs 63.9 MHz for MRI at 1.5 Tesla). However, at high frequencies or at the MRI frequency, the structure is quite different. The impedance of the capacitor at high frequencies is

15 small and is depicted as a short circuit, 21 in FIG 1e. The RF inductors have a large impedance, behaving approximately as open circuits 34, 35. Note that the use of LC resonant reactances 24 and 25 can provide a much higher impedance at the MRI frequency, depending on the circuit Quality factor (Q). The net result is that rather than a two-lead catheter, the catheter now acts as a long loop MRI receiver, 40, which

20 is ideal for tracking. Furthermore, the two catheter electrodes, 14, 15 have been decoupled from the rest of the circuit as depicted in FIG. 1e. Note that the two electrical structures shown in FIG 1d and FIG 1e exist simultaneously, but at different frequency ranges. Therefore, this structure enables the same leads to be used for high resolution MR Imaging, the recording of physiological potentials, and/or RF ablation.

25 [77] In the preferred embodiment, the proximal ends 4 and 5 of the catheter are connected to an MRI tuning, matching and decoupling circuit 99 and signal splitting circuit 100 as exemplified in FIG. 2. FIG. 2a shows a photograph of the circuitry in a prototype system. In the MRI tuning, matching and decoupling circuit 99 (FIG. 2b), reactive elements 70, 71, 74, and 77 are provided such that the catheter loop 40 shown

30 electrically in FIG. 1e and which has an electrical inductance, is tuned to resonate at the MRI frequency when the catheter is engaged in the sample of interest such as the

body. In addition, the reactive elements are adjusted so that the impedance at the catheter MRI output connections 84 and 85 is matched approximately to the characteristic impedance of the transmission cable used to connect the catheter to the receiver input of the MRI system. For example, a 50Ω coaxial cable with BNC type

5 connectors. Alternatively, the catheter MRI output connections 84 and 85 can be connected directly to the receiver input of the MRI system, for example, to the input of a preamplifier. In this case, the impedance should be adjusted to the value that corresponds to the preamplifier input impedance that results in an optimum or near-optimum preamplifier noise figure.

10 [78] It will be understood that the matching circuit shown in FIG. 2b has the advantage of providing a balanced input, analogous to that provided by a balun transformer, by virtue of the two capacitors 74 and 75 connected to both sides of the catheter leads. Suitable tuning and matching circuits for catheter devices are known to those skilled in the art, for example, as described in Atalar et al cited above, and in

15 Ocali O, Atalar E. entitled "Intravascular magnetic resonance imaging using a loopless catheter antenna" in *Magn Reson Med.* 1997;37:112-8, and it will be understood that other matching and tuning circuits that are routinely used for matching and tuning MRI detector coils may be alternatively used and are within the scope of, and foreseen by, the disclosed systems and methods.

20 [79] In addition, the MRI tuning, matching, decoupling and signal splitting circuit (FIG. 2B) shows, e.g., decoupling element 90 including a low noise PIN diode, connected across the output conductors 84 and 85. During MRI excitation by an external transmit coil, a DC bias voltage is provided by the MRI scanner across the coil input causing the PIN diode to conduct. During conduction, the tuning elements

25 are shorted-out, which results in detuning of the catheter loop 40, and high impedance, thereby limiting those RF currents induced at the MRI frequency in the loop.

[80] In previous studies, concerns have been raised about the safety of using metallic structures in MR scanners. Radiofrequency energy (MHz) -transmitted from

30 the scanner in order to generate the MR signal - can be deposited around the interventional device. This results in high electrical fields around the instrument and

local tissue heating. This heating tends to be most concentrated at the ends of the electrical structure. This safety issue can be addressed using the disclosed systems and methods. The concern is that the surface ring electrodes, which directly contact the tissue, can cause local tissue burns. The electrodes need to be cut/removed from

5 the circuit in the megahertz frequency range. This can be accomplished with an inductor circuit element (placed in series) between the lead wires and the surface electrodes. With this design, the electrical end of the leads (in the megahertz range) are buried inside of the catheter and as a result, the concentrated electric fields are also located inside of the catheter, instead of in the tissue. This results in a significant

10 reduction in unwanted tissue heating. A more effective way to 'cut' the surface electrodes from the rest of the circuit could be to use a resonant circuit in place of the inductors. This resonant circuit could include an inductor in parallel with a capacitor (an 'LC circuit'). If this LC circuit is tuned to the MR frequency, it can present a very high impedance at this frequency. This can effectively cut the surface electrodes and

15 reduce unwanted heating. For maximal effectiveness, the LC circuit should be shielded. The LC circuit may be placed distal to the electrodes and allowing the electrodes to be visualized.

[81] In order to monitor physiologic bio-potentials and/or deliver RF energy for ablation, a splitting circuit is required. In FIG. 2b, leads 64 and 65 of splitting circuit

20 100 are connected across the catheter output leads 4 and 5. These leads are connected via RF filters 67 and 68 to either the bio-potential monitoring device and/or the RF energy source for ablation at 94 and 95. The purpose of RF filters 67 and 68 is to prevent spurious electrical noise signals that are at least at or near the MRI frequency, from passing from either the bio-potential monitoring device or the RF energy source

25 for ablation to the catheter system 40. In addition the RF filters can stop RF signals induced by the MRI scanner, for example during excitation, from being input to the bio-potential monitoring device or the RF ablation energy source. The RF filters 67 and 68 can be of a number of types known to those skilled in the art, including but limited to those described in U.S. Patent Application Serial No. 09/428,090, filed

30 November 4, 1999, of which this application is a continuation in part, and in Lardo AC, McVeigh ER, Jumrussirikul P, Berger RD, Calkins H, Lima J, Halperin HR,

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“Visualization and temporal/spatial characterization of cardiac radiofrequency ablation lesions using magnetic resonance imaging”, *Circulation* 2000;102:698-705.

For example, RF filters 67 and 68 can be low pass filters with a cut-off frequency chosen to lie between the MRI frequency of the catheter loop 40, and a lower RF

5 frequency of the RF ablation device so that any signals that arise at the MRI frequency on lines 64 and 65 are significantly attenuated and effectively eliminated.

Alternatively, in another preferred embodiment as illustrated in FIG. 2b, filters 67 and 68 are parallel LC resonant circuits with resonant frequencies adjusted to substantially match that of the MRI frequency. By this means, the impedance of each filter can be

10 rendered a very high value at the MRI frequency depending on the Q of the circuit, thereby stopping or substantially eliminating signals arising on lines 64, 65, 94, 95.

[82] In summary, it will be seen that, with the filtering and connections in place as described, low frequency physiological bio-potentials can pass unimpeded from surface electrodes 14 and 15 to bio-potential measuring device connected at outputs

15 94 and 95. Similarly RF energy for ablation applied at a frequency that is different from the MRI frequency to leads 94 and 95, can be delivered unimpeded to electrodes 14 and 15 when they are used for ablation. Any noise or other signals present at the MRI frequency can be substantially attenuated or effectively eliminated from lines 64, 65, 94, 95. From the MRI standpoint, electrodes 14 and 15 are deactivated and

20 disconnected. The catheter behaves as a loop antenna 40 tuned to the MRI frequency and matched to the MRI system input, 84 and 85. During MRI excitation, or in fact at any point during the procedure when it is desirable to do so, the antenna can be deactivated by a DC bias voltage applied across inputs 84, 85, by virtue of the decoupling means 90.

25 [83] In this embodiment, it will be apparent also that the entire area of the loop antenna 40 extending from the distal portion of the catheter 11 near the electrodes, to the points where the catheter is connected to the MRI tuning, matching, decoupling and splitting circuits 99 and 100, is MRI active. However, a number of situations may arise where it is desirable to limit the length of sensitivity and/or improve the tuning 30 properties of the loop antenna. In particular, the loop 40 is tuned by capacitor 20 in conjunction with the tuning and matching elements 71, 74, and 75 in tuning and

matching circuit 99 at each end of a catheter that may be 100 cm or more long. The extended length of this loop may render it susceptible to stray capacitance arising between the leads of the catheter, 4 and 5, and the surrounding sample and/or environment. The effect of this stray capacitance is generally to add capacitance to the effective LC resonant circuit formed by the loop antenna. If the detuning produced by this effect is significant, it is preferably offset by re-adjustment of the tuning and matching circuit 99. Under situations where the catheter is inserted to different lengths in the sample, different amounts of stray capacitance may occur resulting in variable performance and/or a need for retuning which is not convenient during a procedure or study. In addition there are losses associated with the stray capacitances which can degrade performance as an MRI antenna.

[84] In an embodiment, the effect of the stray capacitance is reduced relative to the total capacitance needed to tune the circuit by adding additional capacitance at other locations. In order not to impede passage of bio-potential and/or RF ablation signals, the capacitors are placed between leads 4 and 5 analogous to capacitor 20. In one embodiment, depicted in FIG. 2C, tuning capacitor 20' is connected across 4 and 5 creating distal portions 4" and 5" and proximal portions 4' and 5'. The entire loop 40 is tuned to resonance via circuitry 99 as above, but now with the 2 capacitors, 20 and 20' present. In another preferred embodiment the placement of capacitor 20' is used to shorten the effective length of loop 40 to a smaller loop 40" of working length L, thereby improving MRI performance by reducing stray capacitance effects and the amount of noise picked-up from the sample. In this embodiment, a section of shielded cable, such as coaxial cable 41 may be used to form the proximal portion 40' of the loop 40. By this means, stray capacitance and noise pick-up associated with the loop section 40' is substantially eliminated. This has no effect on the measurement of bio-potentials or application of RF ablation. In yet another exemplary embodiment shown in FIG. 2d, additional capacitors 20b, 20c, 20d are connected between the catheter leads 4 and 5 to further distribute the MRI tuning capacitance along the MRI-active portion of the catheter L with shielded cable portion 41 connecting this portion to circuitry 99 and 100 described above. In an embodiment, at least one tuning capacitor is provided. In this embodiment, loop 40" is tuned as before. The number

of capacitors that can be added in this way is limited by the inability to tune the circuit if the capacitance becomes too large. In addition the capacitance is preferably limited such that bio-potential and/or RF ablation signals are transmitted without significant impediment between electrodes 14 and 15, and input/output connections 94 and 95.

5 [85] While the catheter devices that are illustrated in FIG. 1 and FIG. 2c and FIG. 2d are depicted with two electrodes 14 and 15, this is not intended to be a limitation. Conventional catheters with different numbers of electrodes, for example with 1-7 electrodes for intra-cardiac use, are available. The multi-functional MRI probe or catheter disclosed herein can be extended to catheters with tips with different numbers 10 of electrodes by placing the capacitor 20 immediately proximal to the plurality of electrodes, in the case of two or more electrodes. In such embodiments, the capacitor is connected across the lead 4a that goes to the proximal electrode 15a, and to any of the leads connected to a more distal electrode such as 14b, as depicted in FIG. 2e. A loop antenna is thereby formed from leads 4a and 5a, which are connected to the 15 circuitry 99 and 100 shown in FIG. 2b, as above. Because the other leads, e.g., leads 7, 8, can be used for measuring bio-potentials, and/or delivering RF energy for ablation thereby they may be filtered and each connected to a filter circuit 100. In addition, performance and safety are improved by providing reactances 24a, 24b, 25a, 25b etc, one for each electrode, of the same form and design as reactances 24 and 25 20 in FIG. 1C3, 1F, or 1G.

[86] FIG. 2F depicts an embodiment in which a probe or catheter may have a single electrode, 15b. A loopless antenna, as described by and Atalar cited above, is formed by providing a shielded coaxial cable length 41" for the catheter section, with an unshielded central conductor portion extending to the single electrode 15b as shown 25 in FIG. 2f. In this single electrode embodiment, the active or "whip" portion of the antenna extends from the electrode over the extending portion 4b, with the proximal end of 4b, and the shield of the coaxial cable fed to inputs 4 and 5 of circuits 99 and 100 shown in FIG. 2b.

[87] In an embodiment, the electrophysiology catheter can be made to function in 30 the mode of a loopless antenna described by Ocali and Atalar cited above, with catheters employing a plurality of electrodes. In a preferred embodiment represented

by FIG. 1b, the distal end 4a of the catheter and distal electrode 14 form the MRI active end of a loopless antenna, and the connecting portions 4 and 5 form a cable portion of same. In this embodiment leads 4 and 5 are preferably formed by a shielded cable section which extends from tuning/matching/decoupling/splitting

5 circuitry 99 and 100 to proximal electrode 15, analogous to the use of cable section 41 used in FIG. 2d described above. In particular, lead 5 is formed by the outer shielding of the coaxial cable and is terminated by the ring electrode 15. The outer shielding of the coaxial cable is insulated from the sample and is only exposed to the sample at ring electrode 15. Similarly, section 4a connected to electrode 14 is electrically

10 insulated so that it is only exposed to the sample via contact electrode 14. Tuning of the loopless antenna via circuitry 99 is as described by Ocali and Atalar cited above, and the splitting circuitry remains unchanged. Note that in this embodiment reactive elements 23-26 may be omitted. In another embodiment, capacitor 20 may be omitted also.

15 [88] During MRI the conducting loops formed by electrodes 14 and 15 in loopless antenna embodiments of the disclosed systems and methods, may introduce decoupling artifacts, or give rise to local heating due to currents induced in the loops by the MRI excitation field. This problem is mainly limited to distal electrode 14 because electrode 15 is attached to the cable shield. In a further embodiment these

20 problems are minimized by electrically cutting the circular electrodes so that they cannot make continuous loops while maintaining continuous connections between the electrode and lead 4a and 5. This will not curtail their performance for measuring bio-potentials or RF ablation. In another embodiment, these problems are minimized by reducing the diameter of the electrodes and by forming the electrodes with a solid area of conductor covering the electrode diameter.

25 [89] Loopless antenna embodiments have an advantage of shielding essentially the entire length of the catheter up to the proximal electrode, from stray capacitance and noise pick-up from the sample. In addition it provides the advantage of an MRI capability with an improved range beyond the proximal electrode 15 to the most distal

30 portion of the catheter, the distal electrode, thereby improving image quality and resolution even closer to the target area.

[90] Embodiments wherein the catheter electrodes are split to form rings as described above and which share the advantages of shielding a substantial portion of the catheter length and maximizing the imaging capability at the distal end of the catheter are further described and illustrated in FIG. 2g, 2h, and 2i. In these 5 embodiments, the electrode rings themselves form loop antennas, and a portion of the catheter is formed by a section of coaxial cable 41", analogous to FIGS. 2d and 2f. A tuning capacitor 20a is connected across the distal end of the coaxial cable section 41a. In this case, the value of the capacitor is chosen, in conjunction with capacitor(s) 29(a, b, etc), such as to tune the loop formed by the distal electrode(s) to resonate at 10 the MRI frequency. One end of each split catheter ring is connected to the next electrode via capacitors, 29, 29a, 29b etc, so that the electrodes together effectively form a helical solenoid with turns that are spaced by the separation of the electrodes. The end of the split ring of the distal electrode is connected back to the other conductor of the coaxial cable, depicted as 5b.

15 [91] FIG. 2G depicts a single electrode loop antenna of this form for use as a multi-functional device. FIG. 2H depicts a two-electrode device. The capacitor 29 can block low frequency currents so that bio-potentials can be measured between the electrodes without being shorted out. For RF ablation, the capacitor is chosen to have a high impedance at the RF ablation frequency, which is preferably much lower than 20 the MRI frequency (eg, <10 MHz compared to about 64 MHz for MRI at 1.5 Tesla) to avoid interfering with MRI signals detection. Fig 2i exemplifies a four electrode device. In this case, the two center electrodes are connected via additional leads 7a, 8a, which need to be connected to filter circuitry 100, as described for FIG. 2e. In FIGS 2g, 2h, 2i, reactances are preferably connected on the DC lines connecting each 25 electrode, as in 24a, 24b, 25a, etc in FIG. 2e and described above in reference to FIG 1C3, 1F, and 1G. While these examples are described in detail some embodiments, it will be seen that this arrangement can be extended to other numbers of electrodes on the catheters, of which it is the intent of the present application to include by reference herein.

30 [92] The multi-functional catheter or probe systems and methods disclosed herein may be constructed so as to be fully MRI-compatible. Specifically, it's design and

materials are selected such that (1) the image is not significantly distorted by the device; (2) the MRI electromagnetic fields do not alter the normal functioning of the device; (3) cardiac arrhythmias or other nerve stimulation affects are not produced by the device, and (4) no damage to the tissue is produced by RF energy received from the MRI scanner. The presence of even small amounts of magnetic material in the imaging fields can produce substantial amounts of image distortion. This distortion is caused by perturbation of the imaging magnetic field. The most distortion is caused by ferromagnetic materials (iron, nickel, cobalt). Little if any distortion is produced by materials that do not become significantly magnetized (low magnetic susceptibility) by the MRI magnetic field. Metals which do not produce significant magnetization include copper, gold, platinum and aluminum among others. Many plastics and synthetic fibers are entirely non-magnetic and do not distort the images.

[93] FIG. 1C shows an embodiment in which the catheter or probe is constructed based on gold-tipped, 1-15 french, most likely 7 french, MRI-compatible two-electrode ablation catheter. MRI-compatible electrode components 14 and 15, such as those used in commercial ablation catheters, or electrodes including, e.g., safe, bio-compatible, minimally corrosive materials such as gold, platinum and the like are suitable for this purpose. Leads 4 and 5 are formed from insulated conducting wire, an insulated section of flexible printed circuit board, or twin lead cable. The conductor separation should be maintained substantially constant along the length of the catheter shaft in order to promote uniform signal sensitivity and to minimize variability in tuning, which can be accomplished by twin lead cable and flexible printed circuit board, bonding an insulated wire pair together, using a twisted pair, by a multi-lumen tube to house the electrodes, by a composite tube formed with multiple lumens for the electrodes, or by separating the pair with spacers at fixed intervals with mechanisms known in the art. The conductor leads can generally be fixed to the electrodes and/or the electrical components by standard soldering or welding techniques. Ceramic chip capacitors and (non-ferrite) RF inductors wound from small diameter copper wire are preferably used for the electrical components throughout.

[94] The shaft of the catheter is typically formed of a polymer tubing that is flexible and can be torqued within the body cavities, such as Teflon, polyolefin,

polyethylene, pebax, polyurethane, or PTFE. The properties of the materials are such that they enable the device to be easily steered under MRI guidance. The diameter of the tubing should be in the range 0.8-5 mm used typically for electrophysiology procedures, or in the range 1-15 french. The total length of the catheter is in the range

5 0.6-2 m, but typically at least 1 m. In embodiments designed for cardiac ablation applications, the length of the invasive portion of the device is preferably at least 1.2 m long so that the tip can be placed into the heart from the femoral artery or vein, and the diameter of the device is approximately 2.5 mm. In the embodiment shown in FIG. 2c and FIG. 2d, section 41 corresponding to loop 40' can be formed from coaxial 10 cable of diameter less than that of the shaft, and connected to circuitry 99 and 100 via standard small gauge RF-type connectors as are known and used by those skilled in the art.

[95] In the loopless antenna embodiment corresponding to FIG. 1b wherein the entire proximal length of leads 4 and 5 up to electrode 15 are formed by a coaxial 15 cable type configuration, similar coaxial cable of diameter less than that of the shaft, and connected to circuitry 99 and 100 via standard small gauge RF-type connectors can be used. Alternatively, the leads can be formed by flexible, torqueable insulated cable replacing the shaft altogether. In this version of the loopless antenna embodiment, the insulating shaft 10 (FIG.1a) is replaced by the external insulation on 20 the shaft. In yet another preferred embodiment, torqueability and maneuverability are enhanced by using coaxial cable formed by a nitinol hypotube. Similarly, the shaft that forms the coaxial cable may be constructed with an inner core that is formed from nitinol, and plated with alternating layers of gold and silver. A layer of insulation made out of FEP or PET could be used to separate the inner core from the outer 25 conductor.

[96] FIG. 3 shows a block diagram illustrating the operation of an MRI scanner system which may be used in connection with the disclosed systems and methods. A magnet is provided for creating the magnetic field for inducing magnetic resonance. Within the magnet are X, Y, and Z gradient coils for producing a gradient in the static 30 magnetic field in three orthogonal directions. Within the gradient coils is an external RF excitation coil. The external RF excitation coil produces the magnetic field to

excite the MRI signals in the body. A computer is provided for controlling all components in the MRI scanner. This includes the RF frequency source, spectrometer and pulse programmer. The pulse programmer generates a carefully-controlled time-sequence of shaped and/or phase or frequency-modulated RF pulses that are delivered

5 to the RF power amplifier. The RF power amplifier has pulse power of 1-20 kW which is applied to the external RF excitation coil. The computer also controls the gradient magnetic field by providing a sequence of modulated pulses that are synchronous with the RF pulse sequence, to gradient power amplifiers, which in turn activate the X, Y, and Z gradient magnetic field coils in the magnet. Signals detected
10 by receiver coils in response to the applied RF/gradient imaging sequences, including those detected in the aforementioned multi-functional MRI catheter system, are first input to a receiver preamplifier. These signals are amplified, phase sensitive detected, for example, by converting to digital signals and being fed to a digital receiver. The digital image data are then reconstructed in the computer and displayed as images on
15 a monitor or the like.

[97] It is important that the location of the tip of the catheter can be accurately determined by MRI. A number of modes of localization can be used. Because the catheter is a receiver it can be used to directly image the tissue around it. This image can be viewed on with high resolution employing a probe or catheter as disclosed
20 herein, or, it can be viewed at low resolution as an overlay on a large field-of-view “scout” image obtained with an auxiliary coil outside the body. The location of the catheter in the body can be tracked by the bright line of signal moving in the scout image. The scout image can be updated at an interval set by the user to compensate for patient motion. An interactive control can allow the physician to “zoom in”
25 towards the bright catheter, finally resulting in a high-resolution image in the area of the distal catheter and tip. The “zoom” function can be achieved with interactive control of the imaging gradients.

[98] Some exemplary embodiments may include a combined multi-functional MRI catheter; a multi-functional MRI catheter connected and used in conjunction with
30 matching/tuning/decoupling circuit means and splitting circuit means; a multi-functional MRI catheter used with said circuit means in conjunction with a bio-

potential monitoring device and/or a standard RF generator for use in ablation connected at inputs 94 and 95 of FIG. 2b; and any of a combined multi-functional MRI catheter and said circuit means used in conjunction with one or more of a bio-potential monitoring device, an RF generator for ablation, and an MRI scanner. In 5 such a system embodiment, the MRI scanner has a receiver whose inputs are connected to inputs 84 and 85.

[99] The probe or catheter disclosed herein can be used in combination with an MRI scanner such that RF energy can be delivered to selected areas of tissue with the electrodes of the multi-functional catheter, bio-potentials measured with the 10 electrodes, the tissue imaged with the antenna portion of the catheter. RF lesions, target tissue, catheter location and tracking may thus be visualized with the use of external detector coils or the catheter-antenna, or using external detector coils in conjunction with the catheter-antenna. This image visualization and bio-potential measurements can be used for (1) precise titration of therapy, (2) the ability to test the 15 length and depth of lesions from new ablation-energy sources, and (3) accurate assessment of the success of making lines of ablation that block conduction.

[100] MRI can also be used to guide other procedures. In Cardiology, accurate anatomic information, combined with electrical measurements, allows improved study of the pathophysiology of arrhythmias, stunning, remodeling, and tachycardia- 20 induced myopathy. Outside of Cardiology, MRI-guided ablation of tumors such as metastatic liver disease, brain tumors, and prostate cancer, may allow treatment with less morbidity and less cost than conventional open surgery.

[101] As an example of the embodiment depicted in FIG. 1c, a 100 cm long prototype catheter device for use in a 1.5 Tesla MRI system was constructed from 25 electrode components taken from a gold-tipped, 7 french, MR-compatible two-electrode ablation catheter (Bard Inc., Murray Hill, New Jersey). The two wire leads were formed from 30 gauge insulated copper wire (0.25 mm wall thickness - AlphaWire Co. Elizabeth, NJ) with a conductor separation held constant at 1.3 mm. For the shaft of the catheter, polyolefin tubing (3.36 mm diameter with 0.5 mm wall 30 thickness - AlphaWire Co. Elizabeth, NJ) was used yielding a final catheter size of 10 french. A 500 pF chip capacitor (1.4 x 1.4 x 1.45 mm) was placed between the

catheter leads 2 cm from the catheter tip (American Technical Ceramics Corp.

Huntington Station, NY). RF tip chokes 24 and 25 were not used in this

implementation. This catheter was connected to circuitry shown in FIG.2b. The

catheter and circuitry are pictured in FIG. 2a.

5 [102] Capacitors could have values in the range of about 1-1000 pF. Inductors could have values in the range of about 100-1000 nH. In an embodiment, the capacitor C and inductor L values can be related by the equation $L=1/(w^2C)$, where $w=2\pi B$, and where B is the resonance frequency, for example, about 64 MHz.

[103] FIG. 4 shows the SNR performance of this example. SNR curve 300 represents that of a probe or catheter used as a standard electrophysiology catheter as in FIG. 1C. SNR curve 310 represents that of a probe with an open circuit such as in FIG. 1B. SNR curve 320 represents that of a probe in which the loop 40 is shorted, as in FIG. 1E. These data suggest that use of the example probe or catheter described above can produce a large gain in SNR compared with a standard catheter. In 15 addition, the prototype catheter has comparable performance to the design model, FIG. 1e, which, unlike the prototype, cannot be used for electrophysiology applications.

[104] FIG. 5 exemplifies visualization and tracking of a prototype catheter. Shown are selected images from a 10-second catheter push acquired with 10 frame/sec, real-time MRI and overlaid on a static, slice-selective roadmap image obtained with a conventional external MRI coil. The location of the catheter is readily visualized by the bright line of signal. Annotations indicate the left ventricle (LV), right ventricle (RV), chest wall, and the superior vena cava (SVC). The catheter starts in the right ventricle and is then pulled up into the right atrium (Panels a & b). As the catheter is 25 subsequently pushed, the tip stays in the atrium and the catheter body flexes (Panel c). The catheter is pulled back further (Panels d & e). In Panels f-g, the catheter is pushed once again, the tip stays in the right atrium, and the catheter shaft flexes. Note that the full length of the catheter can be easily visualized.

[105] FIG. 6 demonstrates the multifunctional operation of a prototype catheter, in 30 the form of intracardiac electrogram recordings acquired concurrent with catheter tracking by MRI. Shown are selected images from a 15-second catheter push

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acquired with a 7 frame/sec, real-time MRI sequence. Annotations indicate the left ventricle (LV), right ventricle (RV), chest wall, and the superior vena cava (SVC). The catheter is initially advanced from the jugular vein down the superior vena cava toward the heart (Panels a & b). Once the catheter arrives in the right atrium, the

5 catheter tip gets stuck and the catheter body begins to flex (Panel c). The catheter is withdrawn several centimeters, the shaft is torqued, and then advanced again (Panels d & e). As the tip is now angled anteriorly, it slips through the right atrium and into the right ventricle (Panels f & g). Note that once the catheter arrives in the ventricle, a large bipolar spike is seen in the intracardiac electrogram. Bipolar endocardial

10 recordings typically show only electrical activation of the myocardium (in the ventricle, these spikes are concurrent with the QRS complex in the body surface ECG). In Panel h, the catheter is positioned and stable in the ventricle. Note that a strong bipolar signal is recorded once the catheter tip arrives in the right ventricle (lower amplitude signal is also seen from the right atrium).

15 [106] MRI data can be used to construct 3D map or images of the areas in the heart or other organs being treated, that have undergone ablation, and the surrounding organ or tissue. Areas of ablation can typically be marked by elevated MRI transverse relaxation time values (T2), or decreased longitudinal relaxation values (TI) during infusion of an MRI contrast agent wherein contrast is enhanced by alteration of such

20 relaxation times. A composite 3D rendering of the organ being targeted can be updated after each ablation and displayed with an appropriate rendering technique. The guidance of the catheter tip to the next site of ablation and/or bio-potential measurement, can be assisted by MRI wherein the physician uses the images to manipulate and steer the catheter, or automatic tracking and feedback could assist that

25 physician to steer the catheter. This feature is facilitated by the current availability of MRI frame rates of 10 frames/s or more, which enables real-time catheter placement, bio-potential measurements and intervention. The lesions may be visualized using standard imaging techniques including the use of contrast agents, as discussed in U.S. Patent Application Serial No. US 99/25858, filed November 4, 1999, entitled "System

30 and method for Magnetic Resonance Guided Electrophysiologic and Ablation Procedures" of which this application is a Continuation In Part.

[107] Electrical activation timing information obtained from bio-potential measurements with the catheter, when combined with catheter localization information, enables accurate activation maps that are most useful in determining, for example, the site of origin of an atrial or ventricular tachycardia in the heart.

5 Activation maps can be superimposed and/or color rendered on anatomically accurate reconstructions of cardiac structure. Spatially accurate voltage data is available from knowledge of the location of each electrode in contact with the myocardium in 3D, as derived from MRI. Thus, electrical data originating from each known electrode position allows generation of activation and voltage maps on true anatomic structures.

10 This provides significant advantages beyond the capabilities of the non-fluoroscopic electroanatomic mapping systems that do not provide accurate anatomic information.

[108] When the ablation/imaging catheter is used for the delivery of ablative radio-frequency energy, the high-resolution image obtained via the present catheter system enables visualization of the ablation lesion and of lesion growth. Again, directional orientation, as well as location, of the catheter tip can be determined in 3D space, and the high-resolution image data can be displayed in any plane, and in particular, in the plane orthogonal to the catheter. Since the image is obtained with the same catheter that is delivering the ablative energy, the orthogonal-plane image displays the lesion at its maximal radius, reducing the chances of underestimation as often occurs with

15 ultrasound. High-resolution visualization of ablative lesions by the multi-functional MRI catheter or probe as disclosed herein allows for documentation of whether or not RF application resulted in successful lesion development and of where lesions have and have not yet been made. This facilitates efficient catheter placement so that RF is applied only to tissue not previously ablated.

20

25 [109] The combination of the high-resolution visualization, bio-potential measurements and/or RF ablation functionality in a single catheter as discussed above makes high-resolution MRI guidance ideal for visualization and verification of ablative lesion lines, particularly in atrial tissue. This is useful for ablation of the re-entrant circuit in typical atrial flutter and is crucial for successful ablation of atrial fibrillation. It has been shown that atrial fibrillation can be eliminated with multiple

30 lines of ablative lesions placed in the right and left atria to emulate the surgical maze

procedure. Failures of the 'percutaneous maze' procedure have resulted primarily from incomplete lesion lines. MRI guidance should allow rapid confirmation of lesion line continuity and avoidance of unnecessary repetition of RF application where tissue has already been successfully ablated.

5 [110] The MRI-guided catheter bio-potential/ablation system offers advantages in ablation of ischemic and idiopathic ventricular tachycardias, ectopic atrial tachycardias, atrial flutter, and atrial fibrillation. Unlike AV node reentry and accessory pathway mediated tachycardia, these other arrhythmias have lower ablation success rates and longer ablation procedure durations, primarily due to difficulties in 10 accurate activation mapping or confirmation of lesion development with conventional equipment. Procedure durations and risk of complications should thus be reduced substantially with the MRI-guided catheter ablation system.

[111] While the disclosed systems and methods have been described in connection with embodiments shown and described in detail, various modifications and 15 improvements thereon will become readily apparent to those skilled in the art. Accordingly, the spirit and scope of the present disclosure is limited only by the following claims.

[112] We claim:

1. A probe, comprising:
 - a first electrode disposed at least partially on the probe surface;
 - a second electrode disposed at least partially on the probe surface;
 - a first conductor electrically coupled to the first electrode;
 - a second conductor electrically coupled to the second electrode; and
 - a reactive element electrically coupling the first conductor and the second conductor.
2. The probe of claim 1, wherein the reactive element conducts a high frequency signal between the first conductor and the second conductor.
3. The probe of claim 2, wherein the high frequency signal has a frequency higher than about 10 MegaHertz (MHz).
4. The probe of claim 1, wherein the reactive element conducts a signal including magnetic resonance imaging frequency energy between the first conductor and the second conductor.
5. The probe of claim 1, wherein at least one of the first conductor and the second conductor conducts a low frequency signal to at least one of the first electrode and the second electrode.
6. The probe of claim 5, wherein the low frequency signal has a frequency of up to about 500 kiloHertz (kHz).
7. The probe of claim 6, wherein the frequency is in the range from about 100 Hertz (Hz) to about 1 kHz.
8. The probe of claim 6, wherein the frequency is about 100 kHz.
9. The probe of claim 1, wherein the reactive element conducts a signal including ablation frequency energy to at least one of the first electrode and the second electrode.
10. The probe of claim 1, wherein the reactive element conducts a signal including biopotential recording frequency energy to at least one of the first electrode and the second electrode.

11. The probe of claim 1, wherein the probe further comprises a lumen.
12. The probe of claim 1, wherein the reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor.
13. The probe of claim 1, wherein the first conductor couples to the first electrode through a reactance.
14. The probe of claim 13, wherein the reactance comprises at least one of an inductor and an LC circuit.
15. The probe of claim 1, wherein at least one of the first conductor, the second conductor, the first electrode, and the second electrode comprises at least one of a magnetic resonance compatible material, a superelastic material, copper, gold, silver, platinum, iridium, MP35N, tantalum, titanium, Nitinol, L605, gold-platinum-iridium, gold-copper-iridium, and gold-platinum.
16. The probe of claim 1, wherein the first conductor and the second conductor are electrically coupled to a tuning/matching/decoupling circuit.
17. The probe of claim 1, wherein the first conductor and the second conductor are electrically coupled to a signal splitting circuit.
18. The probe of claim 1, wherein the first conductor and the second conductor are electrically coupled by at least one capacitor.
19. The probe of claim 1, further comprising a third conductor electrically coupled to a third electrode, and a fourth conductor electrically coupled to a fourth electrode, wherein a first signal including high frequency energy is conducted between the first conductor and the second conductor through the reactive element, and a second signal including low frequency energy is conducted to at least one of the third electrode and the fourth electrode.
20. The probe of claim 1 further comprising a shaft, the shaft including at least one of Kevlar, nylon, Teflon, polyethylene, polyolefin, PTFE, polyurethane, PEBAK, braided Kevlar, and braided nylon.
21. The probe of claim 1, wherein the probe surface is covered by a lubricious coating.

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22. The probe of claim 1, wherein the probe has an outer diameter in the range of about 1 French to about 15 French.
23. The probe of claim 1, wherein the probe has a length in the range of about 50 cm to about 200 cm.
24. The probe of claim 1, wherein the probe further comprises a pull wire.
25. The probe of claim 1, wherein the first conductor, the reactive element, and the second conductor form a loop antenna.
26. The probe of claim 1, wherein the first conductor, the reactive element, and the second conductor form a loopless antenna.
27. A magnetic resonance imaging probe, comprising:
a coaxial cable including an inner conductor and an outer shield; and
a split ring electrode including a first portion and a second portion, the first portion being electrically coupled to the inner conductor, and the second portion being electrically coupled to the outer shield.
28. The probe of claim 27, wherein the inner conductor and the outer shield are electrically coupled by a reactive element.
29. The probe of claim 28, wherein the reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor.
30. A magnetic resonance imaging probe, comprising:
a coaxial cable including an inner conductor and an outer shield;
a first split ring electrode electrically coupled to the inner conductor; and
a second split ring electrode electrically coupled to the outer conductor;
wherein the first split ring and the second split ring are electrically coupled by a first reactive element.
31. The probe of claim 30, wherein the inner conductor and the outer shield are electrically coupled by a second reactive element.

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32. The probe of claim 31, wherein the second reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor.
33. The probe of claim 30, wherein the first reactive element comprises at least one of a high-pass filter, a low-pass filter, a band-pass filter, and a capacitor.
34. A magnetic resonance imaging probe, comprising:
 - a coaxial cable including an inner conductor and an outer shield;
 - a first split ring electrode electrically coupled to the inner conductor; and
 - a second split ring electrode electrically coupled to the outer conductor;
 - a first center split ring electrode electrically coupled to the first split ring electrode and to a first conductor;
 - a second center split ring electrode electrically coupled to the first center split ring electrode and to the second split ring electrode, and also coupled to a second conductor.
35. A magnetic resonance imaging probe, comprising:
 - a first electrode disposed on the probe surface;
 - a second electrode disposed on the probe surface;
 - a first conductor electrically coupled to the first electrode through a reactance;
 - a second conductor electrically coupled to the second electrode through a reactance; and
 - a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor.
36. A system for magnetic resonance imaging, comprising:
 - a magnetic resonance imaging probe, including:
 - a first electrode disposed on the probe surface;
 - a second electrode disposed on the probe surface;

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a first conductor electrically coupled to the first electrode through a reactance;

a second conductor electrically coupled to the second electrode through a reactance; and

a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor;

an interface electrically coupled to the probe, the interface including a tuning/matching/decoupling circuit and a signal splitting circuit; and

an MRI scanner electrically coupled to the interface.

37. A method for simultaneously imaging and ablating a tissue, comprising:

exposing the tissue to a magnetic field, the field including a static component and a gradient component;

placing a probe adjacent to the tissue, the probe including:

a first electrode disposed at least partially on the probe surface;

a second electrode disposed at least partially on the probe surface;

a first conductor electrically coupled to the first electrode;

a second conductor electrically coupled to the second electrode; and

a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor, and low frequency energy is conducted to at least one of the first electrode and the second electrode;

directing low-frequency energy to the probe, the low frequency energy being conducted to the tissue by at least one of the first electrode and the second electrode; and

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receiving high-frequency energy from at least one of the first conductor and the second conductor for imaging at least one of the probe and the tissue.

38. A method for simultaneously imaging a tissue and measuring a bioelectric potential in the tissue, comprising:
 - exposing the tissue to a magnetic field, the field including a static component and a gradient component;
 - placing a probe adjacent to the tissue, the probe including:
 - a first electrode disposed at least partially on the probe surface;
 - a second electrode disposed at least partially on the probe surface;
 - a first conductor electrically coupled to the first electrode;
 - a second conductor electrically coupled to the second electrode; and
 - a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor, and low frequency energy is conducted to at least one of the first electrode and the second electrode;
 - receiving low-frequency energy from the probe, the low frequency energy being conducted from at least one of the first electrode and the second electrode; and
 - receiving high-frequency energy from at least one of the first conductor and the second conductor for imaging at least one of the probe and the tissue.

39. A method for simultaneously imaging a tissue, ablating the tissue, and measuring a bioelectric potential in the tissue, comprising:
 - exposing the tissue to a magnetic field, the field including a static component and a gradient component;

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placing a probe adjacent to the tissue, the probe including:

- a first electrode disposed at least partially on the probe surface;
- a second electrode disposed at least partially on the probe surface;
- a first conductor electrically coupled to the first electrode;
- a second conductor electrically coupled to the second electrode; and
- a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor, and low-frequency and medium-frequency energy is conducted to at least one of the first electrode and the second electrode;

receiving low-frequency energy from the probe, the low frequency energy being conducted from at least one of the first electrode and the second electrode;

directing medium-frequency energy to the probe, the medium-frequency energy being conducted to the tissue by at least one of the first electrode and the second electrode; and

receiving high-frequency energy from the probe, the high-frequency energy including magnetic resonance imaging data.

40. A method for simultaneously imaging and treating a tissue, comprising:

exposing the tissue to a magnetic field, the field including a static component and a gradient component;

placing a probe adjacent to the tissue, the probe including:

- a first electrode disposed at least partially on the probe surface;
- a second electrode disposed at least partially on the probe surface;
- a first conductor electrically coupled to the first electrode;
- a second conductor electrically coupled to the second electrode; and

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a frequency-dependent reactive element electrically coupling the first conductor and the second conductor, such that high-frequency energy is conducted between the first conductor and the second conductor;

delivering a therapy to the tissue; and

receiving high-frequency energy from the probe, the high-frequency energy having magnetic resonance imaging data.

41. The method of claim 40, wherein the therapy comprises at least one of ablation energy, heat, ultrasound energy, a substance discharged through a lumen of the probe, and monitoring the delivering.

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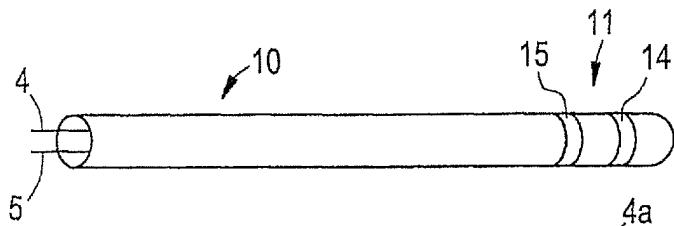


FIG. 1A

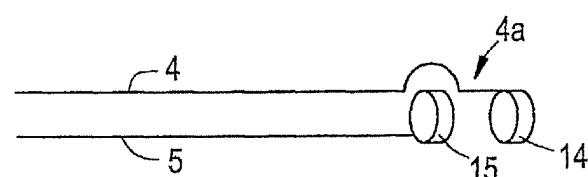


FIG. 1B

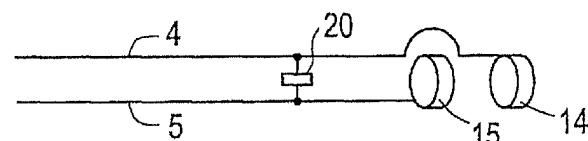


FIG. 1C

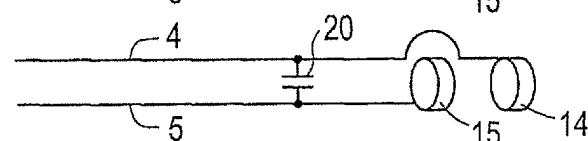


FIG. 1C-1

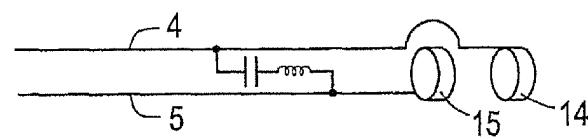


FIG. 1C-2

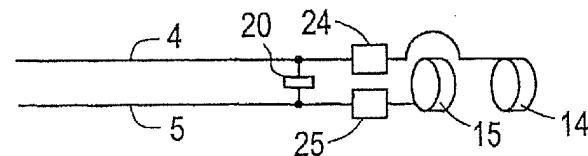


FIG. 1C-3

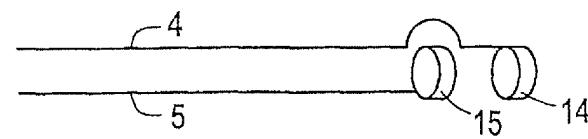


FIG. 1D

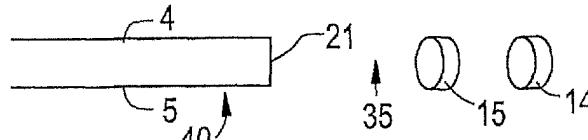


FIG. 1E

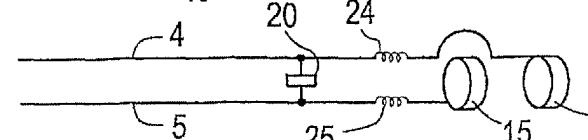


FIG. 1F

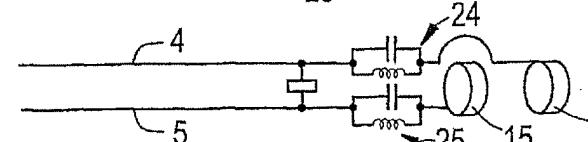


FIG. 1G

FIG. 2A

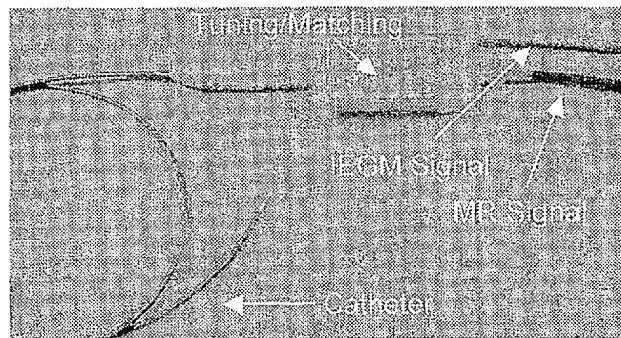
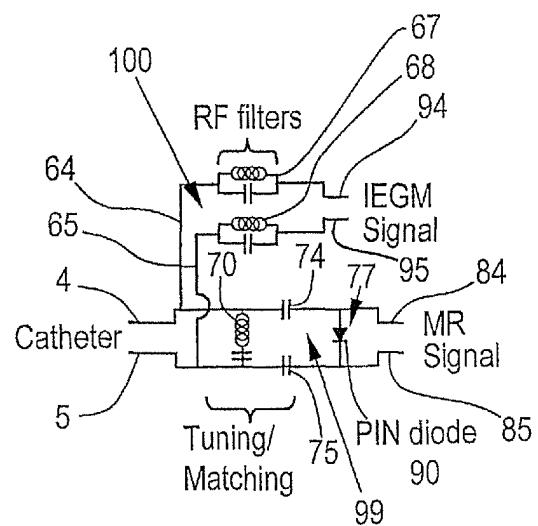


FIG. 2B



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FIG. 2C

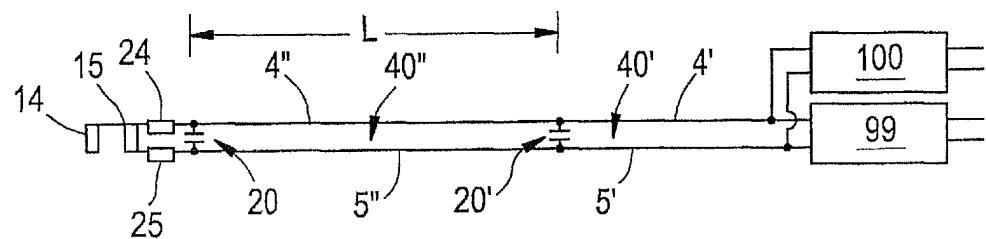
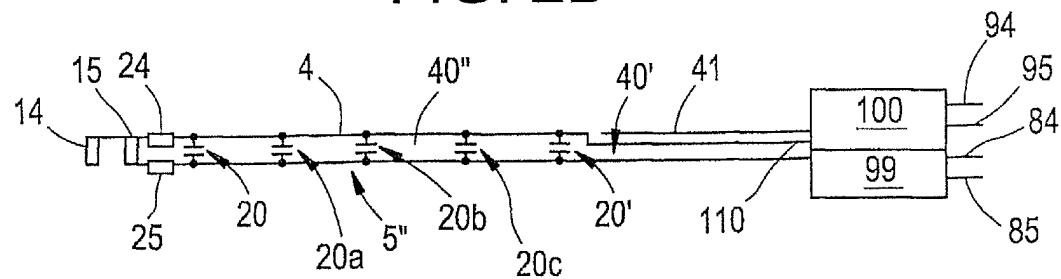


FIG. 2D



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FIG. 2E

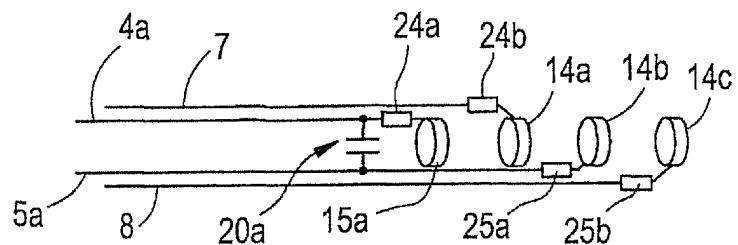


FIG. 2F

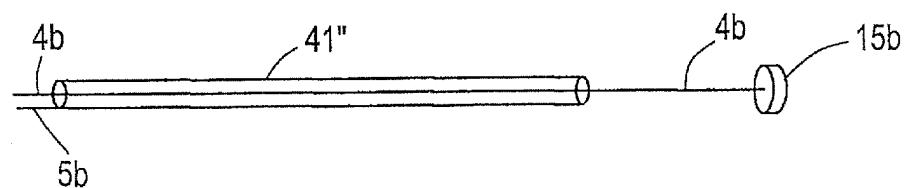


FIG. 2G

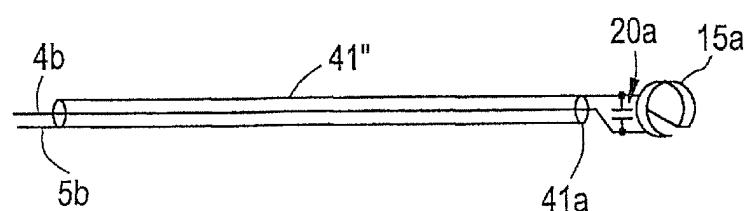
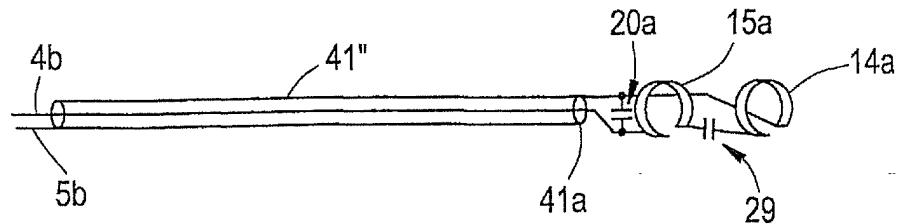


FIG. 2H



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FIG. 2I

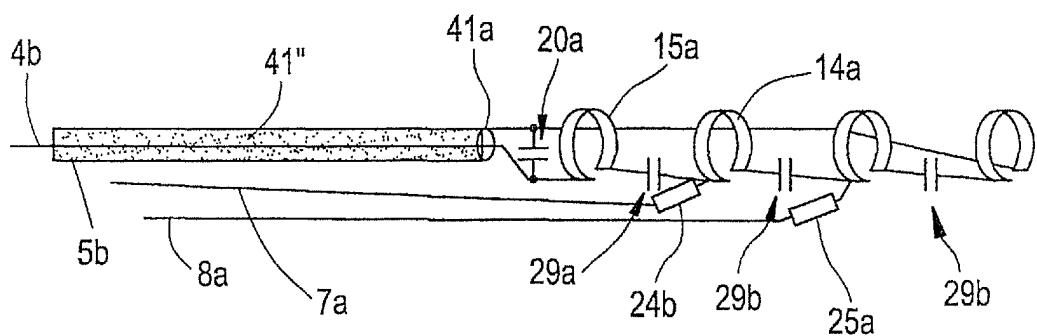
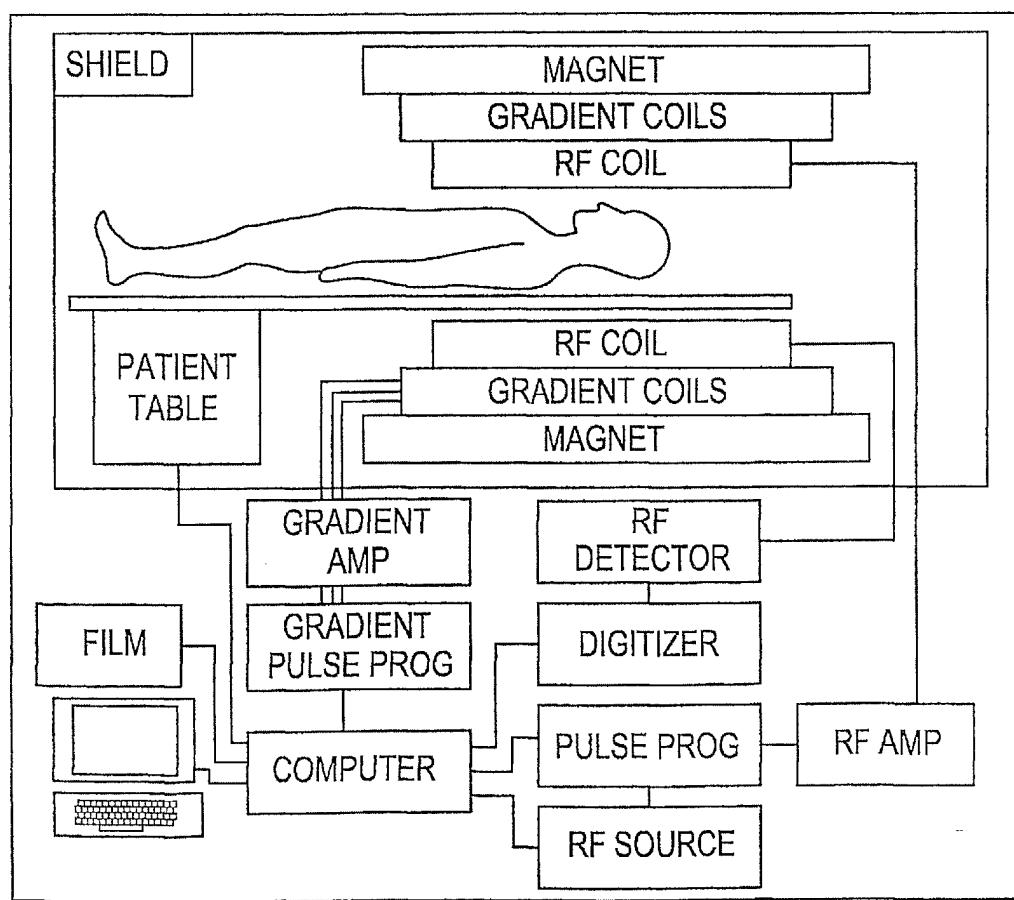


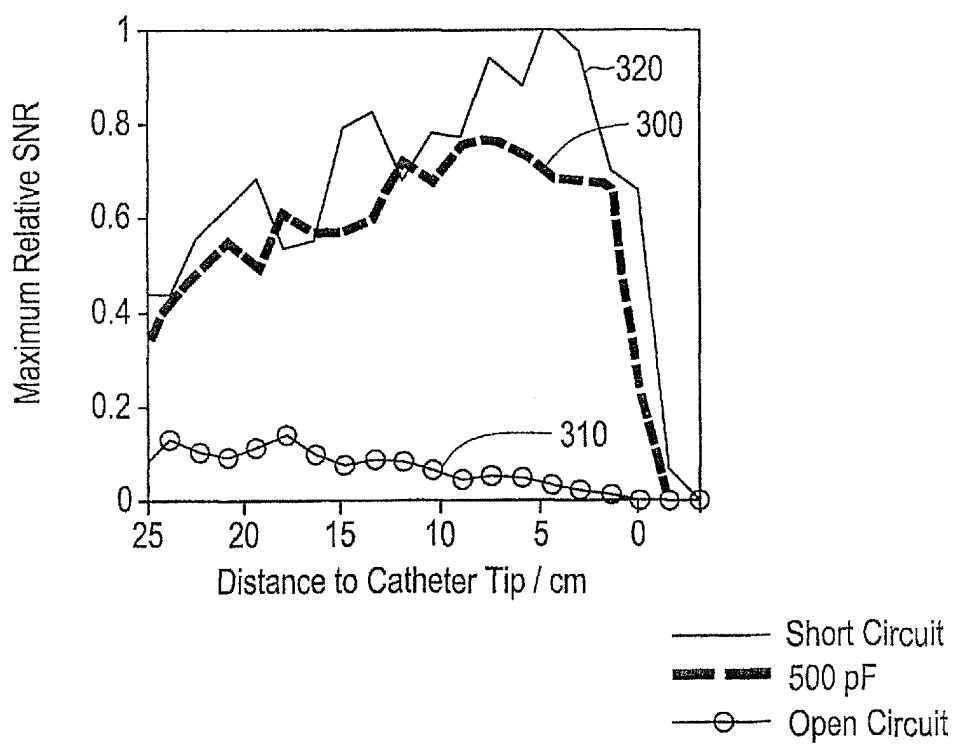
FIG. 3

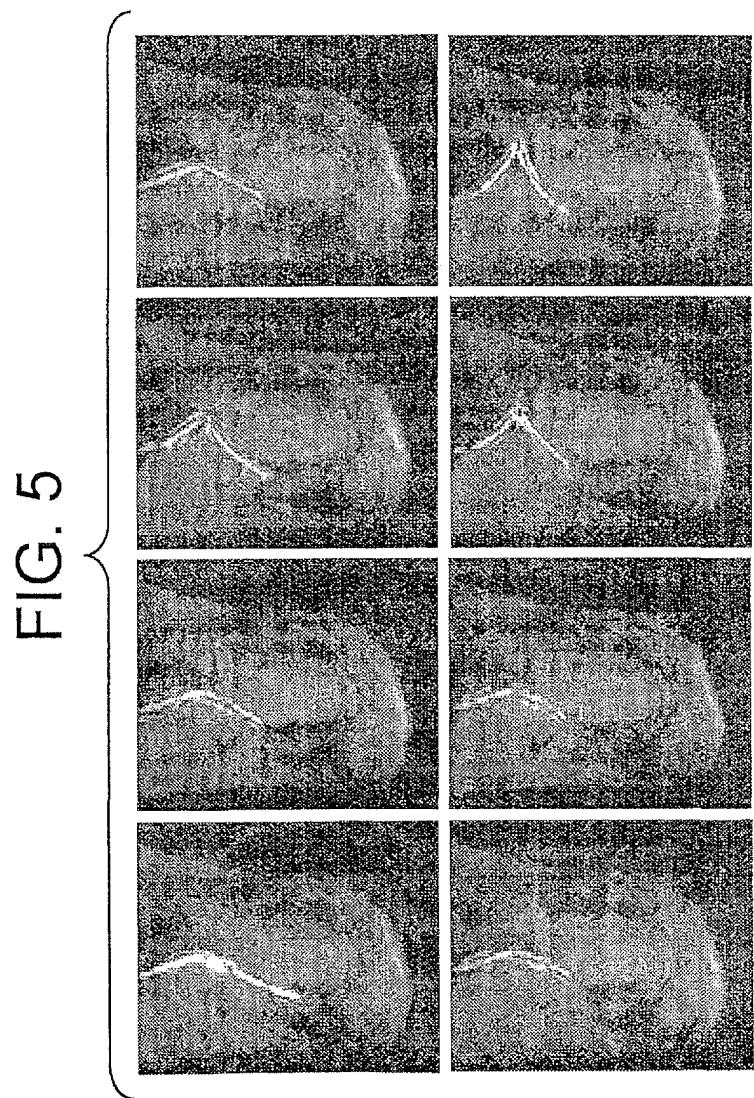


SUBSTITUTE SHEET (RULE 26)

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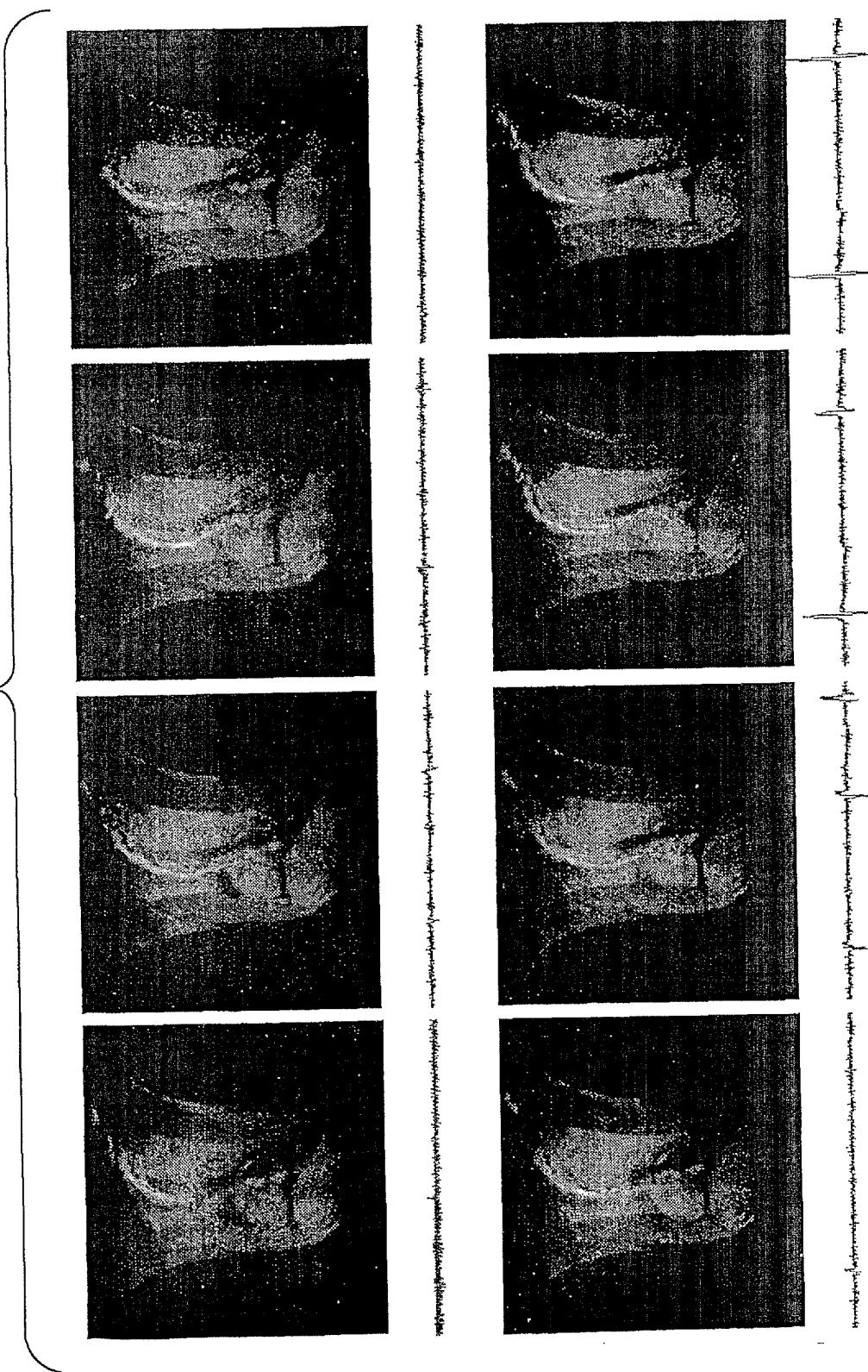
FIG. 4





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FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/11984

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14 A61B5/055

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ^a | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------------------|--|--------------------------------|
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| A | column 8, line 1 - line 28; figures 3,4 --- | 27-36 |
| A | WO 00 25672 A (UNIV JOHNS HOPKINS) 11 May 2000 (2000-05-11) page 13, line 11 - line 18; figure 2 --- | 1,27-36 |
| A | US 6 027 500 A (BUCKLES DAVID S ET AL) 22 February 2000 (2000-02-22) column 3, line 5 - line 21 column 3, line 50 - line 63; figures 1-3 --- | 1 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

^a Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

T later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

g document member of the same patent family

Date of the actual completion of the International search

1 August 2002

Date of mailing of the International search report

08/08/2002

Name and mailing address of the ISA

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Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/11984

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 37-41 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple Inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-26,35,36

probe with two electrodes and reactive element between conductors

2. Claims: 27-34

probe with split ring electrode(s)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/11984

| Patent document cited in search report | | Publication date | | Patent family member(s) | Publication date |
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| US 6027500 | A | 22-02-2000 | NONE | | |